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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/525,126	02/18/2005	Susan Douglas	10914-25	6068
24223 7590 03/28/2007 SIM & MCBURNEY 330 UNIVERSITY AVENUE 6TH FLOOR TORONTO, ON M5G 1R7 CANADA			EXAMINER NIEBAUER, RONALD T	
			ART UNIT	PAPER NUMBER
			1609	
SHORTENED STATUTORY PERIOD OF RESPONSE		MAIL DATE	DELIVERY MODE	
3 MONTHS		03/28/2007	PAPER	

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

## Office Action Summary

Application No.

10/525,126

Applicant(s)

DOUGLAS ET AL.

Examiner

Ronald T. Niebauer

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 26 January 2007.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-48 is/are pending in the application.
- 4a) Of the above claim(s) 1-37, 39-44 and 46-48 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 38 and 45 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 2/18/05 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☒ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date 7/20/06, 1/3/07.
- ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- ☐ Notice of Informal Patent Application
- ☐ Other: \_\_\_\_\_.

## **DETAILED ACTION**

### ***Amendment***

The entry of preliminary amendments including a substitute specification on 8/12/05 is acknowledged.

### ***Election/Restrictions***

Applicant's election of Group III (claims 38, 41-43, 45, and 47) and species of SEQ ID NO:74 (claim 45(i)) in the reply filed on 1/3/07 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

In response to the communication dated 1/26/07 regarding the treatment of the species as a restriction or an election, the examiner is treating the species as an election of species as noted above (election of Group III and species of SEQ ID NO:74). However, it is noted that a finding that SEQ ID NO:74 is allowable does not indicate that the generic claim is also allowed as the generic claim encompasses subject matter beyond the scope of SEQ ID NO:74.

Claims 1-37, 39-44, 46-48 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention/species, there being no allowable generic or linking claim. It is further noted that although Group III includes claims 38, 41-43, 45, and 47 the species election limits the group to claim 38 and claim

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45(i) as the other claims do not read on this species. Further, within claim 45 only (i) reads on the elected species.

The updated claim set submitted on 1/26/07 does not meet the requirements of CRF § 1.121(c). In particular,

'Each amendment document that includes a change to an existing claim, cancellation of an existing claim or addition of a new claim, must include a complete listing of all claims ever presented...'

In the current claim set no record of claims 1-24 is present. Further, for the amended claim text:

'The text of any added subject matter must be shown by underlining the added text. The text of any deleted matter must be shown by strike-through except that double brackets placed before and after the deleted characters may be used to show deletion of five or fewer consecutive characters.'

In the current claim set the amendments made (for example claim 38) are not specified.

Any future submissions that do not comport with the requirements of Rule 1.121 will be deemed non-responsive.

### ***Specification***

The disclosure is objected to because of the following informalities:

The disclosure is objected to because it contains an embedded hyperlink and/or other form of browser-executable code (see for example pages 13, 16, 17, 23 of specification). Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP § 608.01.

Appropriate correction is required.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 45 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claim reads on a peptide 'selected from the group consisting of'. As claimed it is unclear if the peptide consists of (i.e. only contains) the particular sequence or if the peptide comprises the particular sequence (i.e. can have other amino acid residues on either/both sides).

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 38 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claim 38 refers to a polypeptide that is described by amplification of a nucleic acid sequence.

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The following quotation from section 2163 of the Manual of Patent Examination Procedure is a brief discussion of what is required in a specification to satisfy the 35 U.S.C. 112 written description:

The claimed invention as a whole may not be adequately described where an invention is described solely in terms of a method of its making coupled with its function and there is no described or art-recognized correlation or relationship between the structure of the invention and its function. A biomolecule sequence described only by a functional characteristic, without any known or disclosed correlation between that function and the structure of the sequence, normally is not a sufficient identifying characteristic for written description purposes, even when accompanied by a method of obtaining the claimed sequence.

There could be many polypeptides (which could be structurally and functionally different) that could be identified by claim 38. In this case the method of obtaining the sequence does not adequately describe the polypeptide nor does it convey the structure of any peptide that will have antimicrobial function. One of skill in the art would not recognize from the disclosure that the applicant was in possession of the genus of polypeptides of the claimed invention because the description does not give insight into all the possible polypeptides claimed and their characteristics.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

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Claim 38 is rejected under 35 U.S.C. 102(b) as being anticipated by Douglas et al. (as disclosed in IDS (entry #10) although IDS erroneously lists publication date as 2000, the correct publication date is March 2001 (see entry #14)).

Claim 38 is directed to a polypeptide that is encoded by a nucleic acid sequence that is identified by a particular process. For product by process claims section 2113 of the Manual of Patent Examination Procedure states:

"[E]ven though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process."

Douglas et al. teach peptides, more specifically antimicrobial peptides that can be obtained from the genomic DNA of winter flounder (page 138 section 2.1). Using pleurocidin as the initial peptide of interest (page 138 paragraph 3) a nucleotide sequence was identified. Based on the flanking region, oligonucleotides were obtained (figure 1). Pleurocidin like genes were then obtained via amplification (results in figure 2). The end product, an antimicrobial peptide, is obtained from fish and could be identified by the method of the current application. Therefore, the product is the same as or obvious from a product of the prior art so claim 38 is anticipated by Douglas et al.

### ***Conclusion***

No claims are allowed. A search indicates that the elected species of claim 45(i) is free of the prior art.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ronald T. Niebauer whose telephone number is 571-270-3059. The examiner can normally be reached on Monday-Thursday, 7:30am-5:00pm, alt. Friday, EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mary Mosher can be reached on 571-272-0906. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

  
DANIEL M. SULLIVAN, PH.D.  
PRIMARY EXAMINER